



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,424	07/22/2005	Klaus Henning	09600-00028-US	6261
23416 7590 10/31/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
OLSON, ERIC				
ART UNIT		PAPER NUMBER		
1623				
MAIL DATE		DELIVERY MODE		
10/31/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Detailed Action

This action is in response to Applicant's amendment submitted October 2, 2008
After Final.

11. Applicant's request for reconsideration, submitted October 2, 2008, has been fully considered and not found persuasive to put the application in condition for allowance. Applicant argues that the declaration of Henning overcomes the rejection by showing unexpected results for starches having a degree of substitution of over 8%. However, the declaration of Henning only discloses three inventive examples, two hydroxyethyl starches having a degree of branching of 8-10% and one unsubstituted starch having a branching degree of 8-10%. Base claims 1 and 9-13, by contrast, include two types of hyperbranched starches, firstly hydroxyalkyl substituted starches having a degree of branching of 8-20 mol%, and secondly unsubstituted starches having a degree of branching of 11-20%. The declaration of Henning shows no results for inventive unsubstituted starches having a degree of branching of 11-20% as claimed. The only unsubstituted inventive starch shown has a degree of branching of 8-10% which is **below the range included in the instant claims for unsubstituted starches**. Furthermore, the inventive examples only disclose a degree of substitution of up to 0.1, while the claims encompass a degree of substitution of up to 0.3. The comparative examples include CE1 which has a degree of substitution of 0.041 and which lowers its plasma concentration by about 9% over 8 hours, CE2 which is an unsubstituted starch which lowers its plasma concentration by about 59% over 8 hours,

and CE3, which has a degree of substitution of 0.4, above the claimed range, and which lowers its concentration by about 92% over 8 hours, compared to inventive examples 1-3 which lower their plasma concentration by 99.5%, 94%, and 90%, respectively over the same period similar to CE3. The three inventive examples are never compared to starches having a similar degree of substitution. Rather, they are compared to starches with a lower degree of substitution, which display a greater storage effect, and one with a higher degree of substitution, which displays a comparable storage effect. From these data it appears that the degree of substitution is a result-effective variable which must be controlled for to demonstrate any unexpected results. In particular, the high plasma clearance of about 92% displayed by CE3 warrants comparison with other inventive starches having a degree of substitution of up to about 0.3 in order to demonstrate that the unexpected results persist over the entire claimed range. According to MPEP 716.02(d), Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) See also In re Peterson, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003); In re Grasselli, 713 F.2d 731, 741, 218USPQ 769, 777 (Fed. Cir. 1983) In the instant case, the declaration of Henning fails to disclose any results for starches with a degree of hydroxyalkylation of over 0.1%, fails to compare them with any comparative examples

having a degree of hydroxyalkylation over most of the inventive range (0.04-0.3) and fails to provide an inventive example of an unsubstituted starch having a degree of branching actually within the claimed range. Therefore the declaration is not persuasive to remove the rejections of record in the final office action of January 3, 2008.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623

10/29/2008

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623